REMARKS

Claims 1-4, 13, 14, 16-19, and 21-23 have been rejected under 35 USC § 103 as being unpatentable over U.S. Patent 6,016,804 to Gleason et al. in view of U.S. Patent 6,298,849 to Scholey et al. (Scholey). Applicants respectfully submit that this rejection cannot be sustained.

Many respirators that are sold today use a thin rigid structural part to attach filter elements and valves to the respirator mask body. These rigid structural parts are commonly produced through an injection molding process and are often referred to as a "nosepiece" or "rigid insert". A soft compliant material, which is capable of conforming to a person's face, is disposed on or about the rigid structural insert to enable the mask to fit snugly over the wearer's nose and mouth. The use of a rigid insert in conjunction with a soft compliant portion tends to make the mask lighter and more comfortable to wear, particularly when compared to previous masks that had used thick rubber throughout essentially the whole mask body to support the filter cartridges and valves. U.S. Patent 6,016,804 to Gleason et al. shows an example of a rigid insert that would be used in conjunction with a compliant face-contacting member to form a face mask:

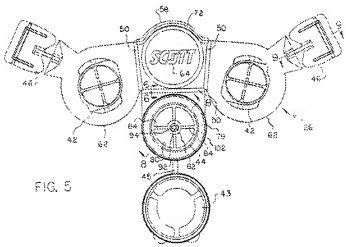


FIG. 5

GLEASON ET AL.

In the above figure, the rigid insert is generally identified using numeral 26.

The rigid structural components that are employed in mask facepieces regularly incorporate multiple integrated elements that have distinct dimensional tolerance requirements and complex shapes that are customarily formed in molds at relatively great expense. Higher

tolerance parts, more-often-than-not, require additional oversight and technical expertise to correctly manufacture. Therefore, for a given material and a given part design, the factor that limits production typically is related to the element that has the greatest tolerance requirement.

To properly utilize the efficiency and accuracy of injection-molding technology, designers have sought to encompass as much detail as possible in the molded part so that the whole rigid structural insert can be manufactured in one step. The Gleason insert 26 is a fine example of such a detailed part. The result of such complexity is that the tooling used is difficult to maintain and operate, especially when used in remote facilities that do not have access to well-trained technical resources. Thus, the higher tolerance requirements for certain portions of the rigid inserts can limit both the design and the production of the whole insert when made using conventional, single-stage, injection-molded technologies. Additionally, when a change to feature in the facepiece insert is needed, such as a different filter mount, a whole new mold must be provided to make the change. That is, a separate mold must be furnished for the whole insert and not simply for a portion of it.

Applicants' invention provides a new method of making a facepiece insert, which method comprises: (a) providing a supporting portion of a facepiece insert; (b) providing a fluid communication component separately from the supporting portion; and (c) securing the fluid communication component to the supporting portion to form the facepiece insert.

Applicants' invention also provides a new method of making a respiratory mask body by securing a compliant face-contacting member to the facepiece insert so produced.

The present invention further provides a new facepiece insert that comprises:

(a) a supporting portion of a facepiece insert; and

(b) a fluid communication component that is non-integrally joined to the supporting portion.

In applicants' invention, the fluid communication components — which commonly are critical tolerance components because they include more complicated and intricate filter attachment mounts and valve seats — are provided in a first step, and, in another step, a supporting portion of a facepiece insert is joined to the fluid communication component.

Applicants' FIG. 3 shows the inventive face piece insert 16, which comprises a supporting portion 34 and a fluid communication components 30, 32:

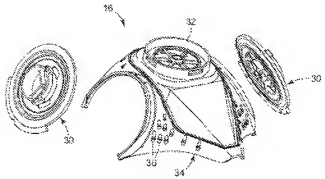


FIG. 3

As shown, the fluid communication components 30, 32 are non-integrally joined to the supporting portion 34. To provide a mask body 12 (FIG. 1), a compliant face-contacting member 14 is provided around the insert 16.

The facepiece insert and its fluid communication components may be made using, for example, injection molding procedures that are carried out as separate operations. The multi-stage operation may address the tolerance mismatch between the insert components. Because the supporting part(s) and the fluid communication part(s) of the insert are separately provided, the inventive method can also support a beneficial distributed manufacturing scheme where fluid communication components can be produced in one location, with the associated expertise and equipment, and the final insert assembly can be carried out in a second location, where the expertise and associated equipment are lacking. And if a change to the fluid communication component is needed, for example, to allow for a different type of filter attachment, the whole facepiece insert does not need to be reconfigured in the mold. A separate mold need only be provided for the fluid communication component of the facepiece insert.

As indicated above, the primary reference to Gleason describes a facepiece insert that is suitable for use with a respiratory mask. As shown in FIG. 4, Gleason's facepiece insert 26 is a single solid part:

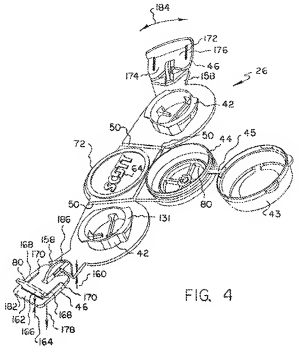


FIG. 4

The fluid communication components 42 and 44 are integrally joined to the supporting portion of the insert 26. Gleason thus, clearly does not recognize the method or respiratory mask of applicants' invention and in fact teaches away from it.

Scholey describes a respirator mask 10 that has a snap-in filter cartridge 24. Scholey's respirator mask 10 includes a mask body 12, an exhalation valve 14, and a strap harness 16:

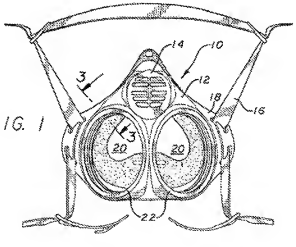


FIG. 1

The mask body 12 is a unitary molded member of a thin rigid plastic and has overmolded portions 18 arranged around the inner face area of the mask to form a rubber-like flange member for supporting and sealing the mask to the face of the user (column 2, lines 43-47). Figures 1a-1c illustrate exploded views of filter cartridges or cartridge assemblies that can be used with the mask of Figure 1:

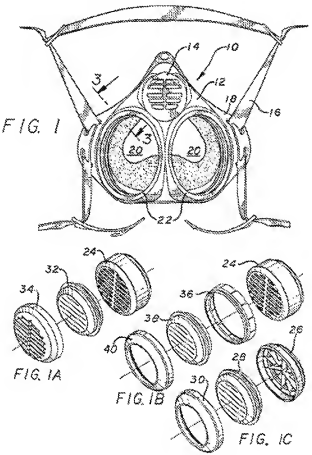


FIG. 1

Scholey states that "[t]he filter cartridges 24 are complete cartridges in themselves, whereas the filter assembly members 26 require additional members such as a replaceable filter member 28 and a cover member 30 to form a total filter assembly."[1]

An overmolded rubber-like flange member 22 is located within each cartridge opening 20 to receive and seal cartridges within the cartridge openings 20:

[1] *See Scholey* at column 2, lines 56-60.

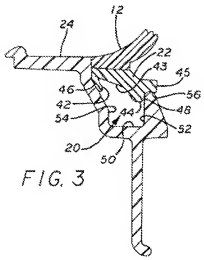


FIG. 3

Two flange members 42 and 44 provide for two sealing surfaces 46 and 48 when used in combination with the filter cartridge 24 or a cartridge assembly member 26.

In the Amendment mailed April 27, 2005, and in an Amendment mailed July 15, 2004, applicants provided amended definitions for the terms "compliant faced contacting member", "face piece insert", and "mask body". Those terms are reproduced below for ease of reference:

> "compliant face contacting member" means the portion of a mask body that engages the facepiece insert directly or otherwise and is compliantly fashioned for making contact with a person's face to allow the mask body to be comfortably supported over a person's nose and mouth.
>
> "facepiece insert" means a rigid element(s) that is fashioned to form part of the mask body but is made separate from the compliant face contacting member to provide structural integrity to the mask body to allow filtration elements and/or valves to be adequately secured thereto.
>
> "fluid communication component" means an element that is structured to allow a fluid to pass from an interior gas space to an exterior gas space or vice versa.
>
> "mask body" means a structure that can fit over the nose and mouth of a person and that can help define an interior gas space separated from an exterior gas space.

The references to Gleason and Scholey do not teach or suggest the present invention because they do not teach or suggest a face piece insert that has separate fluid communication

components. In Gleason, the fluid communication components 42, 44 are integral parts of the face piece insert 26. In Scholey, the mask body 12 does not comprise a face piece insert that has a separate fluid communication component joined to it. In Scholey, the part that the Examiner identifies as a fluid communication component (part 26) is illustrated as being a part of the filter cartridge. Filter assembly member 26 is not joined to the rigid body portion 12. Thus, neither Gleason nor Scholey teach or suggest providing a fluid communication component separately from the supporting portion of a face piece insert. Further, only applicants' invention recognizes the benefits that are entailed when the fluid communication component is provided separately from the supporting portion of the insert. When these parts are made separately, the higher tolerance components can be manufactured in a location where persons are present who have the resources and training to correctly manufacture these parts. The present invention therefore, allows less room for error in manufacturing the higher tolerance parts and is more versatile than known manufacturing techniques. Additionally, a whole new mold does not need to be used when a different filter mount is used in the face piece insert. Therefore, if a different filter cartridge is desired to be used on this same face piece, the manufacturer does not have to fashion a whole new mold for the insert. The manufacturer only needs to make a new mold for the fluid communication component.

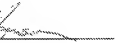
In short, only applicants' invention describes a method of making a rigid insert, where the fluid communication component(s) is provided separately from the supporting portion of the insert. Further, only applicants' invention recognizes the benefits that are entailed when the fluid communication component is so provided. As indicated above, when the supporting portion and fluid communication components are made separately, the higher tolerance components can be manufactured in a location where persons are present who have the resources and training to correctly manufacture these parts. Applicants' invention therefore allows less room for error in manufacturing the higher tolerance parts. Applicants' invention also is more versatile than prior manufacturing techniques in that a whole new mold does not need to be provided when a different filter mount is decided to be employed. If a different filter cartridge is desired to be used on the same facepiece, the manufacturer does not have to fashion a whole new mold for the article.

Because both Gleason and Scholey fail to teach or suggest the basic elements of applicants' invention and also fail to recognize the benefits that are provided by the invention, these references, whether taken alone or in combination, would not have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested.

Respectfully submitted,

January 26, 2007
Date

By: 
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